

Remarks

Reconsideration and withdrawal of the rejections set forth in the Office Action dated March 17, 2004 are respectfully requested. This response is accompanied by a Notice of Appeal.

I. Rejections under 35 U.S.C. §102(b)

Claims 1, 3-6, 8-9, and 16 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Yamamoto *et al.* (EP Patent No. 0 551 169).

Claims 1, 3-9, and 16 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Abra *et al.* (PCT Publication No. WO 98/07409).

These rejections are respectfully traversed.

A. The Present Invention

The present invention describes a method for preparing liposomes having an entrapped compound in the form of a supersaturated solution. The method comprises (i) selecting a compound having a room temperature water solubility capable of at least a two-fold increase when an aqueous solution of the compound is treated by a condition selected from the group consisting of (a) increasing temperature, (b) adding a co-solvent, and (c) changing pH; (ii) preparing liposomes at selected size intervals from a supersaturated solution of the compound; (iii) analyzing the liposomes for the presence (or absence) of precipitated compound; and (iv) selecting liposomes of a size that has no entrapped precipitated compound.

B. The Cited Art

YAMAMOTO ET AL. describe preparation of a liposome composition by the following method:

- (i) preparing an aqueous drug solution of a water-soluble drug by warming the aqueous solvent to yield a solution with the drug in saturated concentration or higher (Col. 2, line 57 to Col. 3, line 7; Col. 4, lines 9-11);
- (ii) forming liposomes while maintaining the solution at the warmed temperature (Col. 3, lines 7-11; Col. 4, lines 25-34); and

- (iii) removing unencapsulated drug, typically by cooling the solution to “ordinary” temperature ((15-25 °C (Col. 3, lines 13-15)); Col. 3, lines 11-13; Col. 4, lines 19-21).

ABRA ET AL. describe a liposomal composition containing an entrapped cisplatin compound (page 1, lines 6-7). To prepare the liposomes, an aqueous cisplatin solution is heated to a temperature sufficient to achieve a two-fold increase in cisplatin solubility over its room temperature solubility (page 3, lines 12-14).

C. Analysis

1. Legal Standard

The standard for lack of novelty, that is, for anticipation, is one of strict identity. To anticipate a claim for a patent, a single prior source must contain all its essential elements. M.P.E.P. § 2131.

2. Analysis of Rejection over Yamamoto *et al.*

Claims 1 and 16 of the present invention are directed to a method of preparing a liposome composition. The method includes, *inter alia*, the steps of (ii) preparing from a supersaturated solution of the compound liposomes at selected size intervals; (iii) analyzing the liposomes for the presence of absence of precipitated compound; and (iv) based on the analyzing, selecting liposomes of a size that corresponds to liposomes having no entrapped preprecipitated compound.

Yamamoto *et al.* do not teach steps (ii), (iii), and (iv) set forth in claim 1 and 16. As noted above, the method of Yamamoto *et al.* is comprised of three steps, preparing a concentrated drug solution, forming liposomes with the concentrated solution; and recovering the unencapsulated drug. Nowhere does Yamamoto *et al.* teach steps of “preparing liposomes at selected size intervals” (claimed step (i)), “analyzing the liposomes as a function of size for the presence of precipitated compound” (claimed step (ii)), and “based on the analyzing selecting a liposome size that corresponds to liposomes having no precipitated compound” (claimed step (iii)).

A. Applicants' Rebuttal to Examiner's Arguments

A1. The Examiner's position is that Yamamoto *et al.* teach selection of the liposomes sizes to maintain the compound in the form of a supersaturated solution because the abstract states that "the supersaturated solution is at the [sic] room temperature". The Examiner goes on to state that "[t]his implies that the compound is not in a precipitated state and this in turn means that the liposomes in the reference have selected liposomal sizes" (Final Office action, sentence bridging pages 2-3).

The Examiner is reminded that anticipation under 35 U.S.C. § 102(b) requires the disclosure of each and every element of a claimed invention, either explicitly or inherently. *In re Schreiber*, 128 F.3d 1473, 44 USPQ2d 1429, (Fed. Cir. 1997).

It is clear that there is no explicit disclosure in Yamamoto *et al.* of the claim steps involving "preparing liposomes at selected size intervals" (claimed step (i)), "analyzing the liposomes as a function of size for the presence of precipitated compound" (claimed step (ii)), and "based on the analyzing selecting a liposome size that corresponds to liposomes having no precipitated compound" (claimed step (iii)).

Thus, it would appear that the Examiner is of the mind that Yamamoto *et al.* *implicitly* discloses the claim steps (ii), (iii), and (iv). The Examiner's statement in the Final Office action that the process in Yamamoto *et al.* "implies the compound is not in a precipitated state and *this in turn* means that the liposomes in the reference have selected liposomal sizes" seems to imply that Yamamoto *et al.* *inherently* includes the missing claim steps.

The legal standard with respect to inherent anticipation is that "inherency may not be established by probabilities or possibilities. The mere fact that a certain thing *may result* from a given set of circumstances is insufficient to prove anticipation." *Contentental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 20 USPQ2d 1746 (Fed. Cir. 1991). *In re Oelrich*, 666 F.2d 578, 212 USPQ 323 (CCPA 1981).

This legal standard requires that the disclosure of the claim steps (ii), (iii), and (iv) which are missing from the explicit disclosure of Yamamoto *et al.*, be necessarily present in Yamamoto *et al.* This legal standard is well illustrated in the case law, and the Examiner is urged to consider the following case illustrations.

In a first case, *Electro Medical Systems v. Cooper Life Science, Inc.* (34 F.3d 1048 (Fed. Cir. 1994); copy enclosed for the Examiner's convenience), anticipation of

a patent to a dental device for cleaning teeth was at issue. The claimed dental device delivered a gas, an abrasive, and a liquid to the surface of a tooth in order to remove plaque and stains. The device directed a stream of abrasive-laden gas to the tooth surface and a stream of liquid to the tooth surface adjacent to the target area of the pressurized gas stream.

A prior art patent to Ruemelin was cited as allegedly anticipating. The lower court had asserted that Ruemelin disclosed every element of the dental device, other than the unpressurized flow of liquid. The lower court had found that this feature was “inherent” in Ruemelin since the device in Ruemelin could be set to any pressure (*Id.* at 1052, [3]).

In reversing, the CAFC found that it was not shown that an unpressurized flow was *necessarily* present in the Ruemelin disclosure, since the mere fact that a certain thing, *e.g.*, unpressurized flow, *may* result *i.e.*, since the device *could* be set to any pressure, was insufficient to prove anticipation.

In a second illustrative case, anticipation of a method of hair removal using a ruby laser, known as an RD-1200 laser, was at issue. *Mehl/Biophile International Cor. V. Milgraum*, 192 F.3d 1362 (Fed. Cir. (1999); copy enclosed for the Examiner’s convenience). The patented method involved aligning a laser light applicator substantially vertically over a hair follicle opening and applying a pulse of laser energy to damage the germ cells (papilla) from which hair grows (*Id.* at 1364, Col. 1).

The manual for the RD-1200 laser was cited as allegedly anticipating the claimed hair removal method. The manual did not explicitly teach “alignment substantially vertically” over a follicle opening; thus the court examined whether such alignment was inherent in the manual’s disclosure (*Id.* at 1365, [4]). The manual taught aiming the laser at skin pigmented with tattoo ink, but there was no disclosed relationship between the location of the tattoo and the location of hair follicles. Therefore, the court found that a laser operator *could* use the laser according to the manual *without necessarily* aligning the laser substantially vertically over a hair follicle opening. The mere possibility of the claimed vertical alignment was insufficient to anticipate the claimed method. (*Id.* At 1365 [5]).

In the present case, Yamamoto *et al.* teach a process of preparing liposomes where the drug “is present in the supersaturated state or in the form of solids or

crystals" (Col. 2, lines 21-23). Because the method of Yamamoto *et al.* *could* be used to prepare liposomes with the drug in solid or crystalline form, it cannot be said that Yamamoto *et al.* inherently anticipates the claimed process of preparing liposomes with the drug in supersaturated form, or that the claim steps (ii), (iii), and (iv) that are undisclosed by Yamamoto *et al.* are inherent in the document's disclosure. The mere possibility of obtaining liposomes with the drug in supersaturated state is insufficient to anticipate the claimed method.

A2. The Examiner also argues that Applicants' previous arguments pertain to the motive of the prior art process and the instant motive; and that since the process and the product formed are the same irrespective of the motivation of employing liposomes in the instant case, Applicants arguments fail (Final Office action, page 3, lines 2-6).

Applicants do not understand how the Examiner arrives at an understanding of Applicants' prior argument as being directed to motive. Nonetheless, the Examiner's point is mistaken in that the claimed process and the process disclosed by Yamamoto *et al.* are not the same. The Examiner is reminded that the instant claims are "method" claims and that the product resulting from the method is irrelevant to the extent that the product is unclaimed.

A3. The Examiner also argues that since Yamamoto *et al.* teach that "the drug is in EITHER supersaturated state or in the form of crystals..." this means Yamamoto must have analyzed the liposomes to see whether there was any precipitation in the liposomes. The Examiner goes on to assert that "since the liposomes containing the supersaturated solutions were analyzed and found to contain no precipitate, the selection of the liposomes is implicit" (Final Office action, page 3, first full paragraph).

The remarks above in section A1 with respect to inherent anticipation apply equally to this argument. Because the liposomes of Yamamoto *et al.* can have the drug in the form of crystals, and there is no teaching or guidance for selection of liposomes only with the drug in supersaturated form, the mere possibility that the disclosure of Yamamoto *et al.* might be understood by one of skill in the art to disclose liposomes in supersaturated condition is insufficient to show that the claimed method steps (ii), (iii),

and (iv) are inherently disclosed therein. One of skill in the art would not necessarily recognize that method steps (ii), (iii), and (iv) are disclosed in Yamamoto *et al.* because Yamamoto *et al.* also teach formation of liposomes containing drug in crystalline form. Thus, the teaching in Yamamoto *et al.* does not inherently anticipate the claimed method.

3. Analysis of Rejection over Abra *et al.*

Abra *et al.* also fail to teach the claimed steps (ii), (iii), and (iv) of selecting a liposome size that corresponds to liposomes having no precipitated compound, of preparing liposomes at selected size intervals; and of analyzing the liposomes as a function of size for the presence or absence of precipitated compound. The disclosure of Abra *et al.* does not inherently anticipate the claimed method, for all the reasons given above in section 2.

Accordingly, Applicants submit that standard of strict identity to maintain a rejection under 35 U.S.C. § 102 has not been met. Withdrawal of the rejections under 35 U.S.C. §102(b) is respectfully requested.

IV. Rejections under 35 U.S.C. §103

Claim 7 was rejected under 35 U.S.C. §103(a) as allegedly unpatentable over either of Yamamoto *et al.* in combination with Woodle *et al.* (US Patent No. 5,013,556). This rejection is respectfully traversed.

A. The Invention

The present invention is described above. Dependent claim 7 includes the additional feature that the lipids for preparation of the liposomes comprise a lipid derivatized with a hydrophilic polymer.

B. The Cited Art

YAMAMOTO ET AL. is described above.

WOODLE ET AL. describe a liposome composition which contains between 1-20 mole percent of an amphipathic lipid derivatized with a polyalkylether, such as polyethyleneglycol.

C. Analysis

According to M.P.E.P. §2142, one of the three requirements to establish a case of *prima facie* obviousness, is that the prior art references teach or suggest all the limitations of the claim.

Claim 1, from which claim 7 indirectly depends, includes the steps of (ii) preparing from a supersaturated solution of the compound liposomes at selected size intervals; (iii) analyzing said liposomes for the presence of absence of precipitated compound; and (iv) based on said analyzing, selecting liposomes of a size that corresponds to liposomes having no preceipitated compound.

As discussed above, Yamamoto *et al.* fail show or suggest a method of preparation that involves claim steps (ii), (iii), and (iv).

Woodle *et al.* is cited merely for the inclusion of lipids derivated with a hydrophilic polymer, and thus provide no teaching of the claimed steps. Thus, the combined teachings of Yamamoto *et al.* and Woodle *et al.* do not show or suggest every feature claimed. Accordingly, dependent claim 7 patentably defines over the teachings of Yamamoto *et al.* in combination with Woodle *et al.* Accordingly, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. §103.

V. Conclusion

In view of the foregoing, Applicants submits that the claims pending in the application are in condition for allowance. A Notice of Allowance is therefore respectfully requested.

If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is encouraged to call the undersigned at (650) 838-4310.

Respectfully submitted,

Date: June 17, 2004

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[18] The jury awarded damages based on the entire market value rule, "which permits recovery of damages based on the value of the entire apparatus containing several features, where the patent related feature is the basis for customer demand." *State Indus., Inc. v. Mor-Flo Indus., Inc.*, 883 F.2d 1573, 1580, 12 USPQ2d 1026, 1031 (Fed.Cir.1989). The entire market value rule is appropriate where both the patented and unpatented components together are "analogous to components of a single assembly," "parts of a complete machine," or "constitute a functional unit," but not where the unpatented components "have essentially no functional relationship to the patented invention and ... may have been sold with an infringing device only as a matter of convenience or business advantage." *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1550, 35 USPQ2d 1065, 1073 (Fed.Cir.1995) (en banc).

[19] Denso argues that the jury could not have reasonably found that (1) the patented and unpatented components comprised a single functional unit and (2) the basis for the customer demand was the method of balancing the fan inside the assembly. Denso's damage expert testified that the motors used with the radiator and condenser assemblies required fans. Denso did not sell these assemblies without fans. Denso's internal documents stress, moreover, that the performance and price of the *entire system* were paramount to its customers. This evidence amply supports the finding that the assemblies were a single functional unit. In addition, the evidence shows that customers wanted fans that were balanced to a certain specification and once Denso abandoned the patented method, it could not meet the 2.0 gm-cm balance specification. Denso argues that its customers did not care how the fans in the assemblies were balanced. However, after Denso changed its specification, one customer complained and required Denso to rebalance the fans. From this evidence, the jury could have reasonably concluded that the demand for

the entire assembly depended on the patented invention.

Thus, the jury properly applied the entire market value rule and Denso failed to demonstrate that the trial court legally erred in denying its motion for judgment as a matter of law or abused its discretion in declining to grant a new trial on the damages issue.

Conclusion

Accordingly, the judgment of United States District Court for the Northern District of Illinois is affirmed.

AFFIRMED



MEHL/BIOPHILE INTERNATIONAL CORP., Selvac Acquisitions Corp. and Nardo Zaias, M.D., Plaintiffs-Appellants,

v.

Sandy **MILGRAUM, M.D.**, Palomar Medical Technologies, Inc., and Spectrum Medical Technologies, Inc., Defendants-Appellees.

No. 99-1038.

United States Court of Appeals,
Federal Circuit.

Sept. 30, 1999.

Rehearing Denied Oct. 27, 1999.

Patentee brought action for infringement of patent claiming method of hair removal using laser. The United States District Court for the District of New Jersey, Alfred M. Wolin, J., 8 F.Supp.2d 434, granted summary judgment of invalidity, and patentee appealed. The Court of Appeals, Rader, Circuit Judge, held that: (1)

patent was not anticipated by instruction manual for laser used to remove tattoos, but (2) patent was anticipated by prior art article.

Affirmed.

1. Patents ⇌72(1)

To anticipate a patent claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently.

2. Patents ⇌72(1)

Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the limitations claimed in a patent, it anticipates.

3. Patents ⇌65

Inherency of patent claim's limitations in a prior art reference, for anticipation purposes, is not necessarily coterminous with the knowledge of those of ordinary skill in the art; artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art.

4. Patents ⇌67.1

Patented method of removing hair by using a laser was not anticipated by instruction manual for laser used to remove tattoos, since manual did not include limitation of aligning laser over a hair follicle opening, and such alignment was not inherent in manual's disclosure, notwithstanding possibility of such alignment.

5. Patents ⇌72(1)

Occasional results are not inherent, for purpose of determining whether patent is anticipated by prior art alleged to inherently include claimed limitations.

6. Federal Courts ⇌762

Appellees always have the right to assert alternative grounds for affirming the judgment that are supported by the record.

7. Patents ⇌70

Patented method of removing hair by using a laser was anticipated by prior art article documenting study of tissue damage induced by laser pulses on epilated backs of guinea pigs, which showed that natural result flowing from the operation as taught would result in alignment of the laser light over a hair follicle, as claimed in the patent, notwithstanding fact that study involved guinea pigs or that article failed to mention hair depilation as a goal.

Jeffrey A. Schwab, Abelman, Frayne & Schwab, of New York, New York, argued for plaintiffs-appellants. With him on the brief were Michael Aschen and Anthony J. DiFilippi. Of counsel on the brief was George A. Arkwright, Schlesinger, Arkwright & Garvey, LLP, of Arlington, Virginia.

Wayne L. Stoner, Hale and Dorr, LLP, of Boston, Massachusetts, argued for defendants-appellees. With him on the brief were William F. Lee and James M. Hall. Of counsel on the brief was Thomas A. Reed, Palomar Medical Technologies, Inc., of Lexington, Massachusetts.

Before MAYER, MICHEL, and RADER, Circuit Judges.

RADER, Circuit Judge.

In this patent infringement action, MEHL/Biophile International Corp., Selvac Acquisitions Corp., and Dr. Nardo Zaias (collectively, MEHL/Biophile) asserted that Dr. Sandy Milgraum, Palomar Medical Technologies, Inc., and Spectrum Medical Technologies, Inc. (Milgraum) infringed U.S. Patent No. 5,059,192 (the '192 patent). On its motion for summary judgment, Milgraum contended that all of the '192 patent claims were anticipated by an instruction manual for the Spectrum RD-1200 laser and by a 1987 Journal of Investigative Dermatology article authored by Dr. Luigi Polla and others (the Polla article). The district court agreed that the manual anticipated the claims, granted summary judgment of invalidity, and dismissed the action. *See Mehl/Biophile Int'l*

Corp. v. Milgraum, 8 F.Supp.2d 434, 47 USPQ2d 1248 (D.N.J.1998). Although this court disagrees that the manual discloses all the elements of the claimed invention, because the Polla article does, this court affirms.

I.

The '192 patent, entitled "Method of Hair Depilation," claims a method for removing hair using a laser. Hairs grow out of hair follicles, tubular apertures in the skin. The collection of germ cells from which hairs grow, known as the papilla, lies at the base of the follicle. The '192 patent claims a method for destroying the papilla, thereby preventing hair regrowth. The written description discloses the use of a Q-switched ruby laser to effect the destruction.

At a meeting of the American Academy of Dermatology, Dr. Zaias visited Spectrum's booth where Spectrum displayed such a laser, known as the RD-1200. Spectrum sold the RD-1200 for use in removing tattoos. Dr. Zaias recognized that the same principles that govern laser absorption in skin pigmented by a tattoo would also focus laser absorption on the natural skin pigment found in the papilla. More specifically, the papilla contains granules (called melanosomes) of a dark pigment (called melanin). A Q-switched ruby laser aimed at the hair follicle will penetrate the skin and reach the papillary melanin. At a particular wavelength, the laser will heat up and destroy the papilla without damaging surrounding tissue.

Claim 1 of the patent, the only independent claim, reads:

1. A method of hair depilation, comprising the steps of:
 - a) aligning a laser light applicator substantially vertically over a hair follicle opening, said applicator having an aperture of sufficient area to surround a hair follicle and overlie its papilla;
 - b) applying through said aperture to the hair follicle a pulse of laser energy of a wavelength which is readily absorbed by the melanin of the papilla and having a

radiant exposure dose of sufficient energy and duration to damage its papilla so that hair regrowth is prevented and scarring of the surrounding skin is avoided.

Dependent claims 2-6 further specify parameters of the laser light applicator, energy delivery, and the type of laser.

MEHL/Biophile sued Milgraum in the United States District Court for the District of New Jersey for infringement of all the claims of the '192 patent. Milgraum moved for summary judgment of invalidity based on 35 U.S.C. § 102 (1994), arguing that two prior art references each teach all the limitations of the claims. As noted at the outset, Milgraum relied on the manual for the RD-1200 laser which describes the use of a laser to remove tattoos. The manual teaches the use of a Q-switched ruby laser to remove a tattoo: "[E]nergy is selectively absorbed only by pigmented chromophores and not surrounding tissue, greatly reducing the risk of scarring."

Milgraum also relied on the Polla article entitled "Melanosomes Are a Primary Target of Q-Switched Ruby Laser Irradiation in Guinea Pig Skin." The Polla article documents "the tissue damage induced by Q-switched ruby laser pulses in black, brown, and albino (control) guinea pigs . . . in an effort to define the nature and extent of pigmented cell injury." The method involves epilating guinea pigs with soft wax, holding the aperture of the laser in contact with the skin, and pulsing the laser. Using an electron microscope, the researchers observed "disruption of melanosomes deep in the hair papillae."

The district court considered both references, but ultimately rested its decision on the RD-1200 manual. MEHL/Biophile appeals. MEHL/Biophile makes several arguments for disregarding the manual as an anticipating reference. For instance, MEHL/Biophile argues that the manual does not teach use of the laser to remove hair at all. Further MEHL/Biophile contends that the manual does not disclose a substantially vertical alignment, a claim element. As for the Polla article,

MEHL/Biophile argues that the reference relates to guinea pig skin and does not mention hair depilation. In addition, MEHL/Biophile contends that the epilation of the guinea pig backs removed the papilla so the laser treatment could not have damaged the papilla.

II.

This court reviews a district court's grant of summary judgment by reapplying the standard applicable at the district court. See *Conroy v. Reebok Int'l, Ltd.*, 14 F.3d 1570, 1575, 29 USPQ2d 1373, 1377 (Fed.Cir.1994). Summary judgment is appropriate only when "there is no genuine issue as to any material fact and . . . the moving party is entitled to a judgment as a matter of law." Fed.R.Civ.P. 56(c). In its review, this court draws all reasonable inferences in favor of the non-movant. See *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986).

[1-3] "To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently." *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir.1997). As this court's predecessor stated in *In re Oelrich*, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981) (quoting *Hansgirk v. Kemmer*, 26 C.C.P.A. 937, 102 F.2d 212, 214, 40 USPQ 665, 667 (1939)) (internal citations omitted):

Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient. If, however, the disclosure is sufficient to show that the natural result flowing from the operation as taught would result in the performance of the questioned function, it seems to be well settled that the disclosure should be regarded as sufficient.

Thus, a prior art reference may anticipate when the claim limitation or limitations not expressly found in that reference are nonetheless inherent in it. See *In re Oelrich*, 666 F.2d at 581; *Verdegaal Bros., Inc. v.*

Union Oil Co. of Cal., 814 F.2d 628, 630, 2 USPQ2d 1051, 1053 (Fed.Cir.1987). Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates. See *In re King*, 801 F.2d 1324, 1326, 231 USPQ 136, 138 (Fed.Cir. 1986). Inherency is not necessarily coterminous with the knowledge of those of ordinary skill in the art. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art. See *id.*, 801 F.2d at 1326.

The RD-1200 Manual

[4] The RD-1200 manual cannot anticipate because it does not teach all the limitations of the claimed invention. Claim 1 includes the step of "aligning a laser light applicator substantially vertically over a hair follicle opening." The parties agree that the manual does not discuss hair follicles, let alone aligning the laser over a hair follicle opening. Thus, the manual does not explicitly teach alignment substantially vertically over a follicle opening. Without explicit teachings of this claim limitation, this court must nonetheless examine whether such alignment is inherent in the manual's disclosure.

[5] The manual teaches aiming the laser at skin pigmented with tattoo ink. The record discloses no necessary relationship between the location of a tattoo and the location of hair follicles. Therefore, an operator of the RD-1200 laser could use the laser according to the manual without necessarily aligning the laser "substantially vertically over a hair follicle opening." The possibility of such an alignment does not legally suffice to show anticipation. See *In re Oelrich*, 666 F.2d at 581. Occasional results are not inherent. Because this court holds that the manual does not inherently teach this limitation of the claimed invention, it does not address MEHL/Biophile's other arguments. To anticipate, a single reference must teach every limitation of the claimed invention. Without an inherent teaching about alignment, the manual does not anticipate the claimed invention.

The Polla Article

[6] Although the district court did not reach the Polla article in its anticipation analysis, "[a]ppellees always have the right to assert alternative grounds for affirming the judgment that are supported by the record." *Datascope Corp. v. SMEC, Inc.*, 879 F.2d 820, 822 n. 1, 11 USPQ2d 1321, 1322 n. 1 (Fed.Cir.1989). Milgraum asserts that the Polla article constitutes such an alternative ground. This court agrees.

[7] As to the "aligning" step, the Polla article does not suffer from the same deficiency as the manual. It is not a question of probabilities as to whether a person of ordinary skill following the teachings of the article will align the laser light applicator over a hair follicle. The researchers focused their study on the epilated backs of guinea pigs. No one disputes that guinea pigs have hairy backs. Indeed, the article itself is replete with references to the irradiation of hair follicles and resulting follicular damage:

At 0.8 J/cm², epidermal lesions were more marked and involved hair follicles 0.3 mm below the skin surface. . . . [L]esions were also present 0.5 mm deep in follicles.

[E]ven at the highest radiant exposure (1.2 J/cm²), brown [guinea pig] skin never showed full-thickness epidermal necrosis and at 0.8 J/cm², follicular damage was observed to a depth of 0.5 mm and at 1.2 J/cm² to a depth of 0.7 mm below the skin surface.

Follicular changes were similar in nature and extent to the epidermal alterations described above, and were associated with melanosome disruption.

Specifically, we have shown that . . . pigmented structures in the deep dermis such as hair follicles are affected. . . .

The article further contains a photograph showing "[f]ollicular changes induced by ruby laser." The changes include disruption of "melanosomes contained within fol-

licular epithelium." Moreover the article specifically mentioned disruption of the hair papillae:

At 0.8 and 1.2 J/cm², individual melanosomes were more intensely damaged and disruption of melanosomes deep in the hair papillae was observed.

Finally, the method of exposing the Q-switched ruby laser to the guinea pig skin also inherently teaches substantially vertical alignment over hair follicle openings:

The collimated laser beam struck a circular aperture, 2.5 mm in diameter, held in contact with the skin of the animals.

The record shows that holding the collimated laser in contact with the skin would align it perpendicular to the skin surface and therefore substantially vertically over follicle openings. Viewed as a whole, this disclosure shows, in the words of *In re Oelrich*, 666 F.2d at 581, that the "natural result flowing from the operation as taught would result in" alignment of the laser light over a hair follicle, as claimed. No reasonable jury could find otherwise.

MEHL/Biophile's remaining arguments concerning the Polla article are unavailing. The Polla article concerns itself with guinea pig, rather than human, skin, but that difference is irrelevant to the anticipation analysis. Nothing in the claim limits the method's reach to human skin. Similarly, the Polla article's failure to mention hair depilation as a goal is similarly irrelevant. MEHL/Biophile does not dispute on appeal that the laser operating parameters disclosed in the article substantially coincide with those disclosed in the patent. Accordingly, to the extent the embodiment in the patent achieves hair depilation, so does the Polla method. Where, as here, the result is a necessary consequence of what was deliberately intended, it is of no import that the article's authors did not appreciate the results. See *W.L. Gore & Assocs. v. Garlock, Inc.*, 721 F.2d 1540, 1548, 220 USPQ 303, 309 (Fed.Cir.1983). Finally, as mentioned earlier, the article itself belies MEHL/Biophile's argument that the wax epilation prescribed by the article resulted in removal of the papilla.

The article specifically states that "disruption of melanosomes deep in the hair papillae was observed." MEHL/Biophile's expert testimony contradicting the plain language of the reference does not create a genuine issue of fact.

Thus, the Polla article anticipates claim 1 of the '192 patent. Because MEHL/Biophile has not separately argued the validity of the dependent claims, the judgment of invalidity as to those claims also stands.

COSTS

Each party shall bear its own costs.

AFFIRMED



AK STEEL CORP., Bethlehem Steel Corporation, Inland Steel Industries, Inc., LTV Steel Company, National Steel Corporation, and U.S. Steel Group—A Unit Of USX Corporation, Plaintiffs Cross-Appellants,

and

Laclede Steel Company, Geneva Steel, Gulf States Steel, Inc. of Alabama, Lukens Steel Company, Sharon Steel Corporation, and WCI Steel, Inc., Plaintiffs,

v.

The UNITED STATES, Defendant-Appellee,

v.

Dongbu Steel Co., Ltd., Pohang Iron & Steel Co., Ltd., Pohang Coated Steel Co., Ltd., Pohang Steel Industries Co., Ltd., and Union Steel Manufacturing Co., Ltd., Defendants-Appellants.

Nos. 97-1116, 97-1169 and 97-1200.

United States Court of Appeals,
Federal Circuit.

Oct. 1, 1999.

Following remand, 879 F.Supp. 1254, in antidumping proceeding concerning

steel products from Korea, Department of Commerce made redetermination. Domestic and foreign producers moved for judgment on agency record. The United States Court of International Trade, Gregory W. Carman, Chief Judge, 941 F.Supp. 119, sustained Department's determination that Korean government had conferred certain countervailable benefits on members of Korean steel industry. On cross-appeals, the Court of Appeals held that: (1) domestic credit provided to Korean steel industry by private Korean lenders could not form basis of imposition of countervailing duties; (2) foreign loans to Korean steel industry did not amount to subsidies; (3) Department's finding that Korean government's construction of infrastructure at industrial estate was countervailable subsidy was supported by substantial evidence; (4) Department's finding that exemption from dockyard user fees was countervailable benefit was supported by substantial evidence; and (5) Department's finding that benefit provided to Korean steel industry by revaluation provisions of Tax Exemption and Reduction Control Act (TERCL) were not countervailable was supported by substantial evidence.

Affirmed in part and reversed in part.

Archer, Senior Circuit Judge, filed dissenting opinion.

1. Customs Duties ⇨85(3)

Court of Appeals reviews decision of Court of International Trade sustaining administrative decision by applying anew the statutory standard of review applied by that court to agency's decision.

2. Administrative Law and Procedure ⇨791

Substantial evidence is more than a mere scintilla, but rather it means such relevant evidence as reasonable mind might accept as adequate to support conclusion.

that FICA is not an appropriate tax within the meaning of the Vaccine Act because Corey could never receive the benefits for which he was taxed.

In addition, Ms. Euken argues that there are exceptions to the rule that FICA tax is deducted from the wages of workers. Where an alternative retirement system is available, according to Ms. Euken, under certain circumstances a worker can opt out of the Social Security system and FICA tax is no longer due. She contends this is essentially the case here because the Vaccine Injury Compensation Trust Fund will provide for Corey, not the Social Security system.

While we are sympathetic to the arguments of Ms. Euken, under a proper construction of the statute they are beside the point. The relevant question is whether workers in the private sector would normally have FICA taxes deducted from their average gross weekly earnings. While there may be narrow exceptions to the rule, it is beyond dispute that the vast majority of workers in the private sector pay FICA taxes from their gross earnings. See 26 U.S.C. § 3101(a) and (b). Moreover, the Vaccine Act, by specifying an objective standard for determining the net amount of the loss of earnings to be awarded unrelated to what any petitioner might be expected to earn, precludes consideration of Corey's particular status. Under these circumstances, the argument that Corey would not receive any Social Security benefits is simply not pertinent to the question of whether FICA taxes are appropriate taxes to deduct from the average gross weekly earnings of a private sector worker. Because we determine that Ms. Euken's arguments, even if the premises underlying them are accepted as true, are not persuasive, we need not consider the Secretary's rebuttal to the contention that an individual such as Corey could opt out of the Social Security system.

Accordingly, we conclude that FICA tax, like federal and state income taxes, is an appropriate tax to deduct in determining a lost earnings award under the Vaccine Act. We reverse the decision of the Claims Court

and remand this case for calculation of an award consistent with this opinion.

REVERSED and REMANDED.



**ELECTRO MEDICAL SYSTEMS,
S.A., Plaintiff-Appellant,**

v.

COOPER LIFE SCIENCES, INC., Dentsply International Inc., and Dentsply Research & Development Corp., Defendants-Appellees.

No. 94-1003.

**United States Court of Appeals,
Federal Circuit.**

Sept. 12, 1994.

Foreign manufacturer sought declaratory judgment of invalidity and noninfringement of defendant dental equipment manufacturer's patents relating to air abrasive equipment used to clean teeth. The United States District Court for the Eastern District of New York, John Lynn Caden, United States Magistrate Judge, found all claims in suit to be infringed and not invalid, and, based on finding of willful infringement, awarded double damages and attorney fees in addition to compensatory damages. Foreign manufacturer appealed. The Court of Appeals, Lourie, Circuit Judge, held that: (1) dental device which discharged substantially unpressurized flow of liquid along with pressurized gas was neither anticipated nor obvious; (2) foreign manufacturer's device infringed various claims of patents held by defendant manufacturer; and (3) finding that foreign manufacturer willfully infringed upon defendant's patents was clearly erroneous, so increased damages and attorney fees were not warranted.

Affirmed in part and reversed in part.

1. Patents \S 312(4)

Invalidity of patent on basis that it was anticipated by previous patent must be proved by clear and convincing evidence. 35 U.S.C.A. \S 102(b).

2. Patents \S 66(1.2)

Anticipation under patent statute requires presence in single prior art disclosure of each and every element of claimed invention and is question of fact subject to review under clearly erroneous standard. 35 U.S.C.A. \S 102(b).

3. Patents \S 66(1.19)

Dental device for delivering gas, abrasive, and liquid to surface of tooth as unpressurized liquid "curtain" surrounding pressurized jet of abrasive-laden gas was not anticipated by prior patent which did not disclose substantially unpressurized flow of liquid. 35 U.S.C.A. \S 102(b).

4. Patents \S 314(5)

Obviousness of subject matter of patent is question of law, based on underlying factual inquiries, which are subject to clearly erroneous standard of review. 35 U.S.C.A. \S 103.

5. Patents \S 16.14

Patent for dental device which delivered gas, abrasive, and liquid to surface of tooth as unpressurized liquid "curtain" surrounding pressurized jet of abrasive-laden gas was not invalid for obviousness, in light of scope and content of prior art, differences between claims and prior art, level of ordinary skill in art, and objective evidence of nonobviousness, including long-felt but unsatisfied need, failure of others, commercial success, copying, and tribute by others. 35 U.S.C.A. \S 103.

6. Patents \S 226.6

Determination of patent infringement requires two-step analysis: claim must be interpreted to determine its scope and meaning, and it must be determined whether accused device is within scope of properly interpreted claim.

7. Patents \S 324.5

Scope and meaning of patent claim is issue of law reviewed de novo.

8. Patents \S 324.55(2)

Whether allegedly infringing device is within scope of properly interpreted patent claim is question of fact, reviewed for clear error.

9. Patents \S 226.7, 235(2)

Claim in patent for dental equipment which delivered stream of abrasive-laden particles to point of use upon surface of tooth by first nozzle, and stream of liquid "adjacent" to point of use by second nozzle, did not require that adjacent streams be separate and independent, thus, claim was infringed by device which delivered combined stream of gas, particles, and liquid to tooth surface.

10. Patents \S 235(2)

Claim in patent for dental equipment which delivered stream of abrasive-laden particles and stream of liquid "converging toward each other," for purpose of cleaning teeth, did not require that streams converge at or near surface of tooth, thus, claim was infringed by device which delivered streams of gas, particles, and liquid that converged immediately after discharge.

11. Patents \S 101(4), 168(2.1)

When meaning of words in patent claim is disputed, specification and prosecution history can provide relevant information about scope and meaning of claim.

12. Patents \S 167(1.1)

Patent claims are not to be interpreted by adding limitations appearing only in specification; thus, although specifications may well indicate that certain embodiments are preferred, particular embodiments appearing in specification will not be read into claims when claim language is broader than such embodiments.

13. Patents \S 235(2)

Claim in patent for method of effecting abrasion of tooth using "water soluble" particles discharged by dental cleaning device, did not require that, under actual operating con-

ditions, particles dissolve immediately upon contact with water before hitting tooth; thus, claim was infringed by device which used abrasive particles with insoluble coating that cracked upon impact with tooth and dissolved upon tooth's surface.

14. Patents ⇨235(2)

Claim in patent for dental device that effected abrasion of tooth and released substantially unpressurized flow of liquid as continuous liquid curtain surrounding pressurized jet of particle-laden gas did not required that "solid" curtain of liquid be created at point water was released and was thus infringed by device which, according to expert testimony and experiments conducted at trial, emitted combined spray surrounded by water curtain.

15. Patents ⇨324.5

Award of increased damages or attorney fees to patentee from infringer is reviewed for abuse of discretion. 35 U.S.C.A. §§ 284, 285.

16. Patents ⇨319(3), 325.11(2.1)

"Willfulness" of patent infringement is shown when, upon consideration of totality of circumstances, clear and convincing evidence establishes that infringer acted in disregard of patent and that infringer had no reasonable basis for believing it had right to engage in infringing acts.

See publication Words and Phrases for other judicial constructions and definitions.

17. Patents ⇨324.55(2)

Existence of willful patent infringement is finding of fact, which will not be disturbed on appeal unless clearly erroneous.

18. Patents ⇨227

Law imposes affirmative duty of due care to avoid infringement of known patent rights of others; duty includes seeking and obtaining competent legal advice before engaging in activity that may result in infringement.

19. Patents ⇨227

Inference that opinion of attorney, rendered prior to conduct of client that infringed another's patent, was unfavorable, does not

preclude consideration of other relevant factors in determining whether infringement was willful.

20. Patents ⇨227

Possession of favorable opinion of counsel rendered prior to client's infringement of another's patent is not essential to avoid determination that infringement was willful, but is important factor to be considered.

21. Patents ⇨312(1.1)

Assertion of attorney-client privilege as to opinion of attorney rendered prior to client's infringement of another's patent does not raise irrebuttable presumption of willfulness.

22. Patents ⇨319(3), 325.11(2.1)

Although foreign manufacturer that infringed patents of dental equipment manufacturer refused to produce opinion of counsel rendered prior to infringing conduct, infringement was not willful, where foreign manufacturer waited six years before selling accused product, while seeking declaration that product was noninfringing, only sold products in face of motions to dismiss for lack of justiciable controversy, and had basis for its arguments on the merits; thus, award of increased damages and attorney fees, which was based on finding of willfulness, could not stand. 35 U.S.C.A. §§ 284, 285.

Preston Moore, Attorney, Morrison & Foerster, San Francisco, CA, argued, for plaintiff-appellant. With him on the brief were Grant L. Kim and James R. Shay.

Dale M. Heist, Attorney, Woodcock, Washburn, Kurtz, Mackiewicz and Norris, Philadelphia, PA, argued, for defendants-appellees. With him on the brief were Albert W. Preston, Jr., John P. Donohue, Jr., Thomas R. Boland and Ellen A. Efros. Of counsel was Edward J. Hanson, Jr.

Before MAYER, LOURIE, and RADER, Circuit Judges.

LOURIE, Circuit Judge.

Electro Medical Systems, S.A. ("EMS") appeals from a judgment of the United

States District Court for the Eastern District of New York holding U.S. Patents 3,882,638, 3,972,123, and 4,412,402 infringed and not invalid, and awarding increased damages and attorney fees based on its finding of willful infringement. *Electro Medical Sys., S.A. v. Cooper Life Sciences, Inc.*, Civ. Action No. CV-86-0607 (E.D.N.Y. Aug. 25, 1993) (final judgment order).¹ We affirm-in-part and reverse-in-part.

BACKGROUND

The three patents in suit² relate to equipment for delivering gas, abrasive, and liquid to the surface of a tooth in order to remove plaque and stain without damaging the tooth surface. The devices claimed in the '638 and '123 patents direct a stream of abrasive-laden gas to a tooth surface and a stream of liquid to the tooth surface adjacent to the target area of the abrasive-laden gas stream. After the abrasive particles impact the tooth, they are taken up by the liquid and then removed in suspension form through the use of a common suction tube. The '402 patent relates to an improved device using abrasive particles that are water soluble, wherein the device delivers air, abrasive, and liquid to a tooth surface as a continuous liquid "curtain" surrounding a pressurized jet of abrasive-laden gas.

Appellant EMS is a Swiss manufacturer of dental equipment, distributing products in over fifty different countries. In 1984, EMS filed suit against appellees Cooper Life Sciences Incorporated, Dentsply International Incorporated, and Dentsply Research & Development Corporation (collectively "Dentsply") in the Northern District of Illinois, seeking a declaratory judgment of invalidity and non-infringement of patents relating to air abrasive equipment used to clean teeth, including those at issue here. The '638 and '123 patents are owned by Cooper and

exclusively licensed to Dentsply. The '402 patent is owned by Dentsply.

Despite EMS's allegations that Dentsply had asserted foreign counterpart patents against EMS and its distributors and had threatened to sue potential United States distributors of EMS's products, Dentsply moved to dismiss for lack of a justiciable controversy. Dentsply contended that it did not intend to charge EMS with infringement of the U.S. patents and that EMS lacked the capacity and intent to sell its products in the United States. The Northern District of Illinois denied Dentsply's motion to dismiss.

In 1986, on motion of the defendants, the Illinois court transferred the claims against Cooper to the Eastern District of New York for reasons of convenience, and severed and stayed the claims against Dentsply because Dentsply had no "presence" in New York. Subsequently, Dentsply was allowed to join the New York action because it by then had acquired rights to Cooper's patent.

Dentsply then initiated an International Trade Commission (ITC) proceeding against EMS and others for alleged patent infringement. After discovery was nearly completed, Dentsply moved to dismiss its ITC claims against EMS, which the ITC did, with prejudice.

In November of 1987, Dentsply again moved to dismiss the district court action, claiming that there was no justiciable controversy. As part of its motion, Dentsply noted that

[at a status conference in September of 1987, the magistrate] strongly recommended that, if EMS truly were interested in a determination of the issues of patent validity and infringement, EMS undertake sufficient acts in the United States to create an actual controversy. [The magistrate] made clear his view that, absent at least one sale by EMS in the United States, the court would dismiss the in-

1. The final judgment order dated August 25, 1993 is based on a memorandum and order dated August 26, 1992 ("*Electro I*"), a memorandum and order on reconsideration dated May 13, 1993 ("*Electro II*"), and a memorandum and order on reconsideration dated August 6, 1993 ("*Electro III*").

2. The '638 and '123 patents, both entitled "Air-Abrasive Prophylaxis Equipment," issued in 1975 and 1976, respectively, naming Dr. Robert Black as inventor. The '402 patent, entitled "Equipment and Method for Delivering an Abrasive-Laden Gas Stream," issued in 1983, naming Ben J. Gallant as inventor.

fringement issue for lack of subject matter jurisdiction. Obviously, the same conclusion applies to the issue of patent validity. Mem. of Points and Auth. of Def. in Support of Motion to Dismiss. The court again denied Dentsply's motion.

In 1990, six years after commencement of this litigation, after the completion of discovery and three months before the scheduled trial, Dentsply threatened to bring a third motion to dismiss for lack of a justiciable controversy. In response, EMS sold six products. Dentsply then amended its answer to add a counterclaim for patent infringement, alleging that EMS was a willful infringer. EMS stipulated in a pretrial order that it "[would] not waive any claim of attorney/client privilege in defense of any allegation of willful infringement or demand for counsel fees." Invoking the privilege at trial, EMS declined to disclose the substance of any advice it received from its counsel prior to the United States sales.

After a full bench trial, the court issued a decision finding all of the claims in suit to be infringed and not invalid, and awarding \$8,752.00 in compensatory damages based on EMS's six sales. Drawing an adverse inference from EMS's refusal to produce an opinion of counsel, the court found that EMS was a willful infringer, and awarded double damages and \$942,528.90 in attorney fees. The award was affirmed on reconsideration. EMS appeals from the judgment of validity and infringement and from the award of increased damages and attorney fees.

DISCUSSION

1. Validity

[1, 2] At trial, EMS challenged the validity of claim 20 of the '402 patent on the basis that it was anticipated by U.S. Patent 2,405,854 to Ruemelin under 35 U.S.C. § 102(b). Anticipation must be proved by clear and convincing evidence. *Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 632, 2 USPQ2d 1051, 1053 (Fed.Cir.), *cert. denied*, 484 U.S. 827, 108 S.Ct. 95, 98 L.Ed.2d 56 (1987). Anticipation under 35 U.S.C. § 102(b) requires the presence in a single prior art disclosure of each and every ele-

ment of a claimed invention, *Lewmar Marine, Inc. v. Barient, Inc.*, 827 F.2d 744, 747, 3 USPQ2d 1766, 1767 (Fed.Cir.1987), *cert. denied*, 484 U.S. 1007, 108 S.Ct. 702, 98 L.Ed.2d 653 (1988), and is a question of fact subject to review under the clearly erroneous standard, *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1574, 227 USPQ 177, 179 (Fed.Cir.1985).

[3] The court determined that EMS had failed to introduce clear and convincing evidence that the Ruemelin patent discloses every element of claim 20. Specifically, the court found that the Ruemelin patent did not disclose a substantially unpressurized flow of liquid or a continuous liquid curtain surrounding the pressurized jet of particle-laden gas. *Electro I*, slip op. at 55. EMS asserts that these features are "inherent" in the Ruemelin patent because, although Ruemelin discloses a blasting and spraying gun utilizing pressurized liquid, the Ruemelin device "could be set to any water pressures."

We do not agree that the subject matter of the claim was anticipated. "The mere fact that a certain thing *may result* from a given set of circumstances is insufficient to prove anticipation." *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268-69, 20 USPQ2d 1746, 1749 (Fed.Cir.1991) (quoting *In re Oelrich*, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA1981)) (emphasis added). EMS was required to prove that an unpressurized flow is necessarily present in the Ruemelin disclosure, and that it would be so recognized by persons of ordinary skill. *Id.* at 1268, 20 USPQ2d at 1749. EMS did not discharge its burden; thus, the district court properly concluded that EMS failed to prove invalidity of claim 20.

[4, 5] EMS also challenged the validity of claims 4, 12, 16, and 21 of the '402 patent on the basis that the subject matter of the claims would have been obvious under 35 U.S.C. § 103. Obviousness is a question of law, based on underlying factual inquiries, which are subject to the clearly erroneous standard of review. *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1568-69, 1 USPQ2d 1593, 1597-98 (Fed.Cir.), *cert. denied*, 481 U.S. 1052, 107 S.Ct. 2187, 95

L.Ed.2d 843 (1987). In a thorough opinion, the magistrate undertook an analysis of the obviousness question, carefully considering the scope and content of the prior art, the differences between the claims and the prior art, the level of ordinary skill in the art, and objective evidence of non-obviousness, including long-felt but unsatisfied need, failure of others, commercial success, copying, and tribute by others. See *Graham v. John Deere Co.*, 383 U.S. 1, 17, 86 S.Ct. 684, 693-94, 15 L.Ed.2d 545 (1966). The court concluded that EMS had not met its burden of demonstrating by clear and convincing evidence that the claimed subject matter would have been obvious to one of ordinary skill in the art.

EMS does not challenge the court's underlying findings here; rather, it merely asserts that "if [the claims] were construed for validity as the district court construed [them] for infringement[, they would be] invalid under 35 U.S.C. § 103." We have considered this assertion and find it unpersuasive. EMS has not convinced us of reversible error in the court's determination that the '402 patent is not invalid.

2. Infringement

The court found that the accused EMS device infringed claims 2 and 3 of the '638 patent, claim 4 of the '123 patent, and claims 4, 12, 16, 20, and 21 of the '402 patent. EMS asserts that the judgment of infringement with respect to the '638 and '123 patents was based on erroneous claim interpretation. With respect to the '402 patent, EMS asserts that the judgment of infringement was based on erroneous claim interpretation and clearly erroneous fact finding.

3. In its entirety, with relevant portions of its parent claim added, claim 2 reads:

[A system for handling and feeding abrasive particles comprising means for mixing abrasive particles with a gaseous stream, first nozzle means for delivering the abrasive laden stream to a point of use, controllable supply means for starting and stopping the abrasive laden stream, second nozzle means in predetermined relation to the first nozzle means for delivering a stream of liquid adjacent said point of use, controllable supply means for starting and stopping the stream of liquid and control means for the supply means including means providing for substantially concurrently

[6-8] A determination of patent infringement requires a two-step analysis. First, a claim must be interpreted to determine its scope and meaning; second, it must be determined whether an accused device is within the scope of the properly interpreted claim. *ZMI Corp. v. Cardiac Resuscitator Corp.*, 844 F.2d 1576, 1578, 6 USPQ2d 1557, 1559 (Fed.Cir.1988). The first step is an issue of law, reviewed *de novo*, and the second is a question of fact, reviewed for clear error. *Minnesota Mining & Mfg., Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1570, 24 USPQ2d 1321, 1330 (Fed.Cir.1992). "A finding is 'clearly erroneous' when although there is evidence to support it, the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed." *United States v. United States Gypsum Co.*, 333 U.S. 364, 395, 68 S.Ct. 525, 542, 92 L.Ed. 746 (1948).

[9,10] Claim 2 of the '638 patent is directed to a system for handling and feeding abrasive particles, and recites a "first nozzle means for delivering the abrasive-laden stream to a point of use" and a "second nozzle means in predetermined relation to the first nozzle means for delivering a stream of liquid adjacent said point of use," the first and second nozzle means being integrated in a common handpiece.³ Claim 4 of the '123 patent recites a dental handpiece for use in the cleaning of teeth, and includes "two fluid discharge orifices . . . being positioned and oriented to discharge streams of the abrasive-laden gas and liquid in the same general direction transversely of the hand grip, with the streams of abrasive-laden gas and liquid converging toward each other."⁴

starting and stopping of the discharge of the gaseous and liquid streams from the nozzle means,] in which the first and second nozzle means are integrated in a common handpiece. Claim 3 contains the following relevant language:

second nozzle means for receiving heated water from the water heater and for delivering a stream of heated water substantially to said point of use....

4. In its entirety, claim 4 reads:

A dental handpiece for use in the cleaning of teeth, the handpiece comprising an elongated

EMS argues that the "second nozzle means" of the '638 claims must deliver a stream of liquid to the tooth surface as a stream *separate and independent* from the abrasive-laden stream delivered by the first nozzle means, which is different from the accused device. Furthermore, EMS argues that the '123 claim only covers a device in which the streams of liquid and abrasive-laden gas converge *at or near the surface of the tooth*, unlike the accused device. EMS relies upon the specifications, which it asserts disclose devices consistent with its asserted claim interpretation. Also, EMS points to the prosecution history of the '638 patent, in which the patentee emphasized that the "nozzle means provid[es] for delivery of the stream of liquid to a point adjacent to the point to which the abrasive is directed," and to the prosecution history of the '123 patent, in which the "convergence" of the streams was emphasized.

Because the EMS device delivers a combined stream of gas, particles, and liquid to the tooth surface, EMS asserts that the device does not infringe the '638 patent as EMS interprets the claims. Furthermore, EMS contends that the accused device delivers streams that converge at the edge of a first nozzle, immediately after discharge and before contact with the tooth's surface, and thus it does not infringe the '123 patent. Dentsply contends that the court properly interpreted the claims and properly found infringement.

[11, 12] Claims speak to those skilled in the art. See *Specialty Composites v. Cabot Corp.*, 845 F.2d 981, 986, 6 USPQ2d 1601, 1604 (Fed.Cir.1988). When the meaning of words in a claim is in dispute, the specification and prosecution history can provide relevant information about the scope and meaning of the claim. *Id.* at 986, 6 USPQ2d at 1604. However, claims are not to be inter-

hand grip having two separate fluid passages extended longitudinally therethrough providing respectively for supply of abrasive laden gas and of a liquid, the hand grip further having a head at one end thereof with two fluid discharge orifices and with two passages respectively and separately connecting said longitudinal passages with the fluid discharge orifices, the orifices being positioned and ori-

preted by adding limitations appearing only in the specification. See *Intervet Am. v. Kee-Vet Lab.*, 887 F.2d 1050, 1053, 12 USPQ2d 1474, 1476 (Fed.Cir.1989) ("No matter how great the temptations of fairness or policy making, courts do not rework claims. They only interpret them.") (quoting with approval *Autogiro Co. of Am. v. United States*, 181 Ct.Cl. 55, 384 F.2d 391, 395-96, 155 USPQ 697, 701 (1967)). Thus, although the specifications may well indicate that certain embodiments are preferred, particular embodiments appearing in a specification will not be read into the claims when the claim language is broader than such embodiments. See *Specialty*, 845 F.2d at 987, 6 USPQ2d at 1605 ("Where a specification does not require a limitation, that limitation should not be read from the specification into the claims.").

Upon review of the two specifications and prosecution histories, we conclude that the court did not err when it determined that the term "adjacent" does not necessarily mean "separate and independent." The '638 claim was properly interpreted to cover a device that delivers a combined air, abrasive, and liquid stream surrounded by a liquid stream such that the abrasive is delivered to a target area on the tooth surface and liquid is delivered adjacent to that area. Similarly, the court properly concluded that the term "converge" does not necessarily mean "converge at the surface of the tooth," and that the claims were properly interpreted to cover a device having streams converging before they reach the tooth surface. The prosecution history does not indicate otherwise. We thus see no error in the court's interpretation of the claims of the '638 and '123 patents and hence its infringement determination.

[13, 14] Claims 4 and 20 are representative of the claims at issue in the '402 patent. Claim 4 recites a method for effecting abrasion using "water soluble" particles.⁵ Claim

ented to discharge streams of the abrasive laden gas and liquid in the same general direction transversely of the hand grip, with the streams of abrasive laden gas and liquid converging toward each other.

5. With relevant portions of its parent claim added, claim 4 reads:

20 recites a device for effecting abrasion including "means for releasing a substantially unpressurized flow of [] liquid as a *continuous liquid curtain* surrounding [a] pressurized jet of particle-laden gas." ⁶ EMS argues that neither the "water soluble" nor the "continuous liquid curtain" limitation is satisfied by the accused device.

EMS contends that the meaning of the term "water soluble," as used in the patent, requires that under actual operating conditions the particles dissolve immediately upon contact with the water before hitting the tooth. EMS further contends that the "means for releasing liquid as a liquid curtain" must create a "solid" curtain of liquid at the point the water is released. EMS maintains that the court clearly erred in determining that the abrasive particles used by the EMS device were soluble within the meaning of the claims because they include an insoluble coating that "cracks" upon impact with the tooth so that the particles will dissolve only at the tooth's surface. EMS further maintains that the court clearly erred in determining that the EMS device includes a "means for releasing liquid as a liquid curtain" as that phrase is properly interpreted.

Upon review of the '402 specification and prosecution history, we conclude that the court properly construed the claims as not requiring that the particles used be soluble within the area between the nozzle and the tooth and as not requiring that the curtain of water be a "solid" curtain. See *Specialty*, 845 F.2d at 981, 6 USPQ2d at 1601; *Intervet*, 887 F.2d at 1050, 12 USPQ2d at 1474.

The court's findings of infringement of the '402 patent were based primarily on expert testimony and experiments conducted during the trial. As the court noted, EMS

"performed no tests[, with the exception of an unreliable courtroom demonstration,] to rebut the findings made by Dentsply's expert. [EMS's] lack of 'hard' evidence ... and the plethora of opinion testimony unsupported by any backup evidence, [were] largely unpersuasive." *Electro I*, slip op. at 18-19. Based on the expert testimony and experiments, the court found that the particles used in the EMS device were indeed soluble within the meaning of the claims and that "[t]he inner combined spray emitted from the EMS products' nozzle is surrounded by a water curtain." We conclude that EMS has not shown the court's claim interpretation to be in error or its infringement findings to be clearly erroneous.

3. Increased Damages and Attorney Fees

After determining that the accused device infringed Dentsply's patents, the court assessed actual damages of \$8,752.00 resulting from the six sales in 1990. The court drew an adverse inference from EMS's refusal to produce an opinion of counsel, stating

Based upon EMS' refusal to disclose the substance of the opinion of its counsel, despite Dentsply's charge of willful infringement, as well as EMS' failure to enter the U.S. market for six years after obtaining counsel, the court concludes that it must draw an adverse inference that the opinion was unfavorable. EMS eventually proceeded with knowledge of the unfavorable view of counsel, and thus engaged in willful infringement of the patents.

Electro I, slip op. at 79. The court thus held that the infringement was willful, awarding increased damages and \$942,528.90 in attorney fees. On reconsideration of the award, the court affirmed. *Electro II*, slip op. at 20. After the original and reconsideration orders

6. Claim 20 reads:

[A method for effecting abrasion comprising delivering from a nozzle orifice a pressurized jet of particle-laden gas, with resultant development of an ambient induction zone, releasing a substantially unpressurized flow of the liquid into an annular space surrounding the ambient induction zone and thereby establish a combined stream of gas, particles and liquid, and directing the combined stream against the surface to be abraded,] in which the particles are water soluble and the liquid is water.

Equipment for effecting abrasion comprising: nozzle means for delivering a pressurized jet of gas laden with particles, with resultant development of an ambient induction zone, and means for delivering a liquid into said induction zone comprising means for releasing a substantially unpressurized flow of the liquid as a continuous liquid curtain surrounding the pressurized jet of particle-laden gas.

were issued, EMS offered to waive the attorney-client privilege and disclose the advice of its counsel. The district court declined EMS's offer as untimely.

EMS argues that the award of increased damages and attorney fees must be reversed because it is based on a clearly erroneous finding of willfulness. Dentsply asserts that the court properly awarded such damages and argues that "EMS could have avoided willfulness and ... attorney fees ... had they shown conviction in their case by either selling the product or by waiving privilege." We agree with EMS.

[15] In appropriate cases, a patentee may recover from an infringer increased damages and attorney fees. 35 U.S.C. §§ 284, 285 (1988); *General Motors Corp. v. Devex Corp.*, 461 U.S. 648, 654, 103 S.Ct. 2058, 2061-62, 76 L.Ed.2d 211 (1983). The decision whether to award increased damages or attorney fees is reviewed for an abuse of discretion. *SmithKline Diagnostics, Inc. v. Helena Lab. Corp.*, 926 F.2d 1161, 1165 n. 2, 17 USPQ2d 1922, 1925 n. 2 (Fed.Cir.1991). Such awards have been made when the infringement was found to be willful. *Read Corp. v. Portec, Inc.*, 970 F.2d 816, 826, 23 USPQ2d 1426, 1435 (Fed.Cir.1992).

[16, 17] Willfulness is shown when, upon consideration of the totality of the circumstances, clear and convincing evidence establishes that the infringer acted in disregard of the patent, that the infringer had no reasonable basis for believing it had a right to engage in the infringing acts. See *American Medical Sys. Inc. v. Medical Eng'g Corp.*, 6 F.3d 1523, 1530, 28 USPQ2d 1321, 1325 (Fed. Cir.1993), *cert. denied*, — U.S. —, 114 S.Ct. 1647, 128 L.Ed.2d 366 (1994). The existence of willful infringement is a finding of fact, which will not be disturbed on appeal unless it is clearly erroneous. *Id.* at 1530, 28 USPQ2d at 1325.

[18-20] The law imposes an affirmative duty of due care to avoid infringement of the known patent rights of others. *L.A. Gear Inc. v. Thom McAn Shoe Co.*, 988 F.2d 1117, 1127, 25 USPQ2d 1913, 1920 (Fed.Cir.), *cert. denied*, — U.S. —, 114 S.Ct. 291, 126 L.Ed.2d 240 (1993). Usually, this duty in-

cludes seeking and obtaining competent legal advice before engaging in activity that may result in infringement. *Underwater Devices, Inc. v. Morrison-Knudsen Co.*, 717 F.2d 1380, 1389-90, 219 USPQ 569, 576 (Fed.Cir. 1983). Accordingly, we have held that when an infringer refuses to produce an exculpatory opinion of counsel in response to a charge of willful infringement, an inference may be drawn that either no opinion was obtained or, if an opinion was obtained, it was unfavorable. See, e.g., *Fromson v. Western Litho Plate & Supply Co.*, 853 F.2d 1568, 1572-73, 7 USPQ2d 1606, 1611 (Fed.Cir.1988); *Kloster Speedsteel AB v. Crucible Inc.*, 793 F.2d 1565, 1579-80, 230 USPQ 81, 91 (Fed.Cir. 1986), *cert. denied*, 479 U.S. 1034, 107 S.Ct. 882, 93 L.Ed.2d 836 (1987). However, there are no hard and fast rules in respect of willfulness. *Rolls-Royce Ltd. v. GTE Valeron Corp.*, 800 F.2d 1101, 1109, 231 USPQ 185, 191 (Fed.Cir.1986); *Studiengesellschaft Kohle, M.B.H. v. Dart Indus.*, 862 F.2d 1564, 1573, 9 USPQ2d 1273, 1282 (Fed.Cir.1988) ("The consequences of a finding of willful infringement being serious, such a finding ... is to be made only after due consideration of the totality of the circumstances."). An inference that an opinion was unfavorable does not foreclose consideration of other relevant factors. Possession of a favorable opinion of counsel is not essential to avoid a willfulness determination; it is only one factor to be considered, albeit an important one. *Kloster*, 793 F.2d at 1579, 230 USPQ at 91 (though it is an important consideration, the absence of an opinion of counsel alone does not mandate an ultimate finding of willfulness).

[21] EMS had a right to assert the attorney-client privilege. See *Quantum Corp. v. Tandon Corp.*, 940 F.2d 642, 644 (Fed.Cir. 1991) (attorney-client privilege is a "basic, time-honored privilege [warranting] careful consideration."). As we previously have noted,

[a]n accused infringer ... should not, without the trial court's careful consideration, be forced to choose between waiving the privilege in order to protect itself from a willfulness finding, in which case it may risk prejudicing itself on the question of

liability, and maintaining the privilege, in which case it may risk being found to be a willful infringer if liability is found.

Id. (suggesting that court inspect *in camera* privileged communications to determine if separate trial on willfulness issue is appropriate).⁷ Assertion of the privilege does not raise an irrebuttable presumption of willfulness. Such a rule would not accommodate consideration of other facts, nor would it respect the right of a party to assert the privilege.

[22] The district court here was free to draw an inference adverse to EMS when, asserting the attorney-client privilege, EMS refused to produce an opinion of counsel. However, the court erred because it failed to consider the evidence in its entirety and erroneously evaluated the significance of EMS's six-year delay in entering the market.

The district court reasoned that EMS's decision to wait six years before it sold the accused product supported the inference that EMS possessed an unfavorable opinion of counsel. This suggests that EMS was pursuing protracted litigation and running up large fees to the detriment of its opponents, while believing that it had a losing case and before it infringed. If that were true, such conduct could have been dealt with by sanctions for bad-faith litigation or even dismissal for lack of a case or controversy, but it would not have been willful infringement. There was no finding of misconduct in this case, nor did the district court choose to dismiss the suit. Even if it had an unfavorable opinion of counsel, we agree with EMS that under the circumstances, its decision to defer sale of the accused product was more consistent with satisfying its duty of due care to avoid or minimize infringement than with willfulness. EMS sought a judicial determination of the contested issues before selling the accused product. It was only in the face of three motions to dismiss, two denied and one threatened, and in light of the magistrate's statement that, "absent at least one sale by EMS in the United States, the court would dismiss the infringement issue for lack of subject matter jurisdiction," that EMS sold

six devices. The infringement therefore was *de minimis* and was accomplished only to avoid dismissal and ensure prompt adjudication, not as part of its business to generate income. EMS's conduct throughout the litigation was to seek resolution of the controversy. See *Minnesota Mining & Mfg., Co. v. Norton Co.*, 929 F.2d 670, 673, 18 USPQ2d 1302, 1305 (Fed.Cir.1991). This case does not involve a "wanton disregard of the patentee's patent rights." See *Read*, 970 F.2d at 826, 23 USPQ2d at 1435.

On reconsideration, the district court further stated that "EMS's failure to produce an exculpatory legal opinion gives rise to the inference that it proceeded with this lawsuit against the advice of counsel. It is on this basis that the findings of willfulness and 'an exceptional case' were made." *Electro II*, slip op. at 20. However, filing suit is not willful infringement. Moreover, EMS testified as to its good faith belief that the patents were either invalid or not infringed. Although we have affirmed the court's determinations of infringement and validity, it is clear to us that EMS had a basis for its arguments on the merits. Dentsply itself agreed at oral argument that "there were definitely arguments" with respect to the issues in this case. The questions were indeed close, and this was another relevant factor overlooked in the assessment of willfulness. See *Paper Converting Mach. Co. v. Magna-Graphics Corp.*, 745 F.2d 11, 20, 223 USPQ 591, 597-98. (Fed.Cir.1984) (willfulness finding is generally inappropriate when the infringer mounts a good faith and substantial challenge to the existence of infringement). The facts here do not constitute clear and convincing evidence of willfulness. Upon review of the evidence in its entirety, we are left with the definite and firm conviction that the court erred in finding willful infringement.

"The paramount determination in deciding to grant enhancement and the amount thereof is the egregiousness of the defendant's conduct based on all the facts and circumstances." *Read*, 970 F.2d at 826, 23 USPQ2d at 1435. Absent willful infringement, there is no basis in this case for increased dam-

sever liability from damages.

7. In the present case, no motion was made to

ages. The court expressly declined to find that EMS had engaged in misconduct or copying. *Electro I*, slip op. at 72-73, 79-80 n. 24. See *Read*, 970 F.2d at 826-27, 23 USPQ2d at 1435-36 (listing factors to be considered in determining whether to award increased damages). These factors, in addition to those discussed above with respect to willfulness, compel the conclusion that the award of increased damages was an abuse of discretion. See *Kloster*, 793 F.2d at 1580, 230 USPQ at 91 ("[i]f infringement [is] ... innocent, increased damages are not awardable for infringement."). Likewise, the award of attorney fees, based on an erroneous finding of willfulness, cannot stand. See *Stu-diengesellschaft*, 862 F.2d at 1579, 9 USPQ2d at 1287 (where judge rejected master's willfulness finding, it was proper to reverse the award of increased damages and attorney fees).

CONCLUSION

That part of the judgment holding U.S. Patents 3,882,638, 3,972,123, and 4,412,402 infringed and not invalid is affirmed. That part of the judgment awarding increased damages and attorney fees is reversed because the court's finding of willful infringement was clearly erroneous.

COSTS

Each party shall bear its own costs.

**AFFIRMED-IN-PART and RE-
VERSED-IN-PART.**



**F. Brantley SCOTT and John
H. Burton, Appellants,**

v.

Roy P. FINNEY, Appellee.

No. 94-1090.

United States Court of Appeals,
Federal Circuit.

Sept. 14, 1994.

In interference proceeding involving self-contained penile implant invention, the Board of Patent Appeals and Interferences, interference No. 102,429, awarded priority to senior party on grounds that junior party failed to show reduction to practice before senior party's date of invention. Junior party appealed. The Court of Appeals, Rader, Circuit Judge, held that junior party sufficiently demonstrated reduction to practice through videotape of insertion of prototype into penis of anesthetized patient, which showed surgeon manipulating implanted device several times to successfully simulate erection.

Reversed and remanded.

1. Patents \S 314(5), 324.5

Issue of reduction to practice of invention is question of law which Court of Appeals reviews de novo.

2. Patents \S 113(1)

Court of Appeals reviews Board of Patent Appeals and Interference's factual findings under clearly erroneous standard.

3. Patents \S 90(5)

To show prior invention, junior party must show reduction to practice of invention before senior party, or, if junior party reduced to practice later, conception before senior party followed by reasonable diligence in reducing it to practice; to show reduction to practice, junior party must demonstrate that invention is suitable for its intended purpose.